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TITLE: Potential VCA Candidates, Caregivers, and Providers Motivations, Expectations, and Shared Decision-Making in VCA

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CONTRACTING ORGANIZATION: Mayo Clinic, Rochester MN

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14. ABSTRACT Information regarding the medical, surgical, psychological issues associated with VCA has been gathered from clinicians and patient subjects and analyzed utilizing qualitative research methods and is being curated and incorporated into the conversation aid prototype, paying particular attention to presenting the information in a patient accessible way that facilitates discussion, reflection, and decision making. An oral presentation titled <i>"The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations"</i> was given at the International Conference on Communication in Healthcare by Ian Hargraves PhD to introduce this concept to the scientific community. We believe that this prototype will serve as a first-in-world structured platform for supporting clinicians, candidates, and caregivers through the hand and face transplant decision-making process. Drawing on Mayo Clinic expertise in transplant medicine and psychiatry, immunosuppressive care, shared decision making, qualitative methods, and human-centered design, we are completing an initial prototype web-based tool that facilitates candidate-clinician hand transplant decision making that addresses the upsides and downsides of VCA, potentially conflicting desires of candidates and other stakeholders, the goals of VCA, the practicalities that are needed be problem-solved, and the existential significance of limb-loss and transplant.					
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1. INTRODUCTION

The Potential VCA Candidate, Caregivers and Provider’s Motivations, Expectations and Shared Decision Making in VCA Study began three years ago with the aim to understand the motivations, preferences and values of individuals with upper limb loss and significant facial disfigurement who may be candidates for hand or face transplant. This research is critical to the success of the field of vascularized composite transplantation (VCA) because—although the world experience in VCA is small with only approximately 35 face transplants and 150 upper extremity transplants performed—some transplant recipients have been significantly dissatisfied with the outcome, in some cases leading to noncompliance and graft loss. Improved patient selection and communication about the risks and benefits of VCA is needed to provide this treatment option to those most suited and most likely to succeed. To this end, our study is utilizing qualitative research techniques to understand the perceptions, hopes, and expectations of upper limb loss and facially disfigured patients, their caregivers, and their providers. Following completion of the qualitative discovery of themes that emerge from these interviews, we are investigating strategies, by developing a decision aid prototype, to improve communication between potential VCA candidates and providers in considering treatment options. We believe that improving the communication of choices, understanding the possible outcomes, and considering the potential lifestyle and side effect profile of treatment options will facilitate decision making and improve outcomes in VCA.

2. KEYWORDS

Vascularized Composite Transplantation, qualitative research, hand and face transplantation, motivation and preferences

3. ACCOMPLISHMENTS

What were the major goals of the project?

Aim 1

Major Task 1

Subtask 1: Prepare Regulatory documents and Research Protocol for local and other recruitment centers.

Subtask 2: Submit the Mayo IRB approval and necessary documents for HRPO approval.

Subtask 3.1: Recruit, consent, and enroll 5 patients and caregivers with VCA.

Subtask 3.2: Recruit and consent patients with upper extremity amputations or facially disfigured patients and their caregivers who are evaluated for transplantation.

Subtask 3.3: Recruit and consent patients and caregivers who are potentially eligible for transplantation.

Subtask 4: Conduct in-depth interviews with VCA transplant patients and caregivers.

Subtask 4.1 Conduct in-depth interviews with upper extremity amputees and facially disfigured patients and their caregivers.

Subtask 5: Transcribe and de-identify interviews and analysis, and report interview of VCA transplant recipients and caregivers and subjects from subtasks 3.2 and 3.3.

Subtask 6: Conduct in-depth interviews of the transplant team providers.

Subtask 8: Transcribe and de-identify interviews and analysis of provider interviews.

Major Task 2: Ethnographic observation.

Major Task 3: Manuscript preparation.

Aim 2

Major Task 1

Subtask 1: Enroll subjects, providers, and caregivers from Aim 1 for Aim 2.

Subtask 2: Enroll new patients at the time of their appointments.

Subtask 3: Conduct observations of treatment or treatment follow-up discussions.

Major Task 2

Subtask 1: Synthesize the learnings from Major Task 1 and develop prototypes.

Major Task 3

Subtask 1: Begin use of prototypes.

Major Task 4

Subtask 1: Synthesize the observations of Conversation aid prototypes.

Subtask 2: Begin use of the reviewed prototypes and conduct observations and brief follow-up with clinicians and patients to determine the effectiveness of the prototype.

Major Task 5: Disseminate the prototype to participating clinicians and partnering sites.

Major Task 6: Manuscript describing the Conversation Aid Development.

What was accomplished under these goals?

Specific Aim 1 Accomplishments

Subtask 1: IRB approval was received from the Mayo Clinic and HRPO for a modification that involved self-referral (snowball sampling) of non-Mayo subjects including veteran populations and transplant recipients transplanted at other institutions. HRPO approval was obtained for the study. Modifications are pending approval with HRPO. 100% accomplished for the initial preparation of documents.

Subtask 2: IRB approval was received for the study; 100% accomplished for initial IRB and HRPO study approval.

Subtask 3.1: We have recruited 5 VCA patients and 0 caregivers (5 of 5, 100% accomplished for recipients; 0 of 5, 0% for caregivers).

Subtask 3.2: We consented 2 Mayo subjects and a total of 3 caregivers (2/15 or 13% for transplant evaluated patients and 3/15 or 20% for caregivers). The 2 additional candidates that we attempted to contact have still not returned calls to discuss the study.

Subtask 3.3: We have recruited and consented 13 patients eligible for VCA (13/15, 86% accomplished). We have recruited and consented 6 caregivers of eligible patients (6/15, 40% accomplished).

Subtask 4.: We have conducted 5 interviews with VCA patients (100% accomplished, 0% with caregivers).

Subtask 4.1: Conduct in-depth interviews with upper extremity amputees and facially disfigured patients and their caregivers. We have conducted 1 interview with a transplant candidate and 1 interview with a caregiver (6% accomplished, 6% for caregivers).

Subtask 4.2: We have completed 10 interviews with transplant eligible subjects (10/30 or 33% accomplished) 6 caregivers have been interviewed (6/30 or 20% transplant eligible caregivers interviewed).

Subtask 5: Transcribe and de-identify interview and analysis, and report on interviews.

5 recipient interviews, transcribed and fully coded

1 candidate interview, transcribed and fully coded

1 candidate caregiver interview, transcribed and fully coded

11 eligible interviews—5 bilateral, 5 unilateral, 1 face, all transcribed and coded

7 eligible caregivers, all transcribed, all open coded, level 1

Subtask 6

We have completed 18 in-depth provider interviews. In our DOD grant narrative, we planned for 12 provider interviews and have completed 12/12 (100%). We subsequently received IRB/HRPO and DOD permission to expand this group to 30 and have completed 18 interviews.

10 Mayo providers have been interviewed

- a. 10 have been transcribed
- b. 10 have been fully coded

8 Non-Mayo providers have been interviewed

- a. 8 transcriptions are completed
- b. 8 have been fully coded

Subtask 7: This subtask was deleted during the revision process prior to final DOD approval.

Subtask 8: Transcription of in-depth provider interviews is completed, and analysis is completed (100 % completed).

Major Task 2: Ethnographic observation. 10/10 100 % completed for the chart review.

Major Task 3: 3 manuscripts related to the qualitative interview analysis of 10 subjects with limb loss, provider qualitative interviews, and a case series from our retrospective review of the findings from previous transplant candidates are well underway. When we complete the prototype and have tested it, we plan to publish on this outcome as well.

Specific Aim 2 Major Accomplishments

Major Task 1

Subtask 1: Enroll patients from Aim 1. We have enrolled one subject, their caregiver and provider.

Subtask 2: Enroll patients at the time of their appointments with providers. We have enrolled one subject, their caregiver and provider and consented another subject and two caregivers.

Subtask 3: We have observed one subject, their caregiver and provider.

Major Task 2

Subtask 1: Development of the conversation aid prototype is well underway and will soon be completed.

Major Task 3

Subtask 1: Will begin after completion of Major Tasks 1 and 2.

Major Task 4:

Subtask 1: Will begin after completion of Major Tasks 1-3.

Subtask 2: Will begin after completion of Major Tasks 1-3.

Subtask 3: Will begin after completion of Major Tasks 1-3.

Major Task 5: This will begin after completion of Major Tasks 1-4.

Major Task 6: This will be completed once we have field tested the prototype.

Other Achievements

Dr. Jowsey-Gregoire presented at the American Transplant Congress 2021 IMPACT Session: Psychosocial and Bioethical Aspects of VCA: An Update on Medical Decision Making for VCA Candidates and introduced the concept of purposeful shared decision making to the transplant community. An oral presentation by Ian Hargraves, PhD, titled "*The Application of the Purposeful Shared Decision-Making Schema*

to Hand Transplant Conversations” was presented at the International Conference on Communication in Healthcare, October 20, 2021.

What opportunities for training and professional development has the project provided?

Due to COVID, opportunities to present at national meetings and enlist trainees has been limited. We have included Briana Sanchez, Post Baccalaureate Program and Montserrat Leon Garcia, Visiting Predoctoral Graduate student as part of our research team.

How were the results disseminated to communities of interest?

Our research team has presented at the American Transplant Congress as well as at the International Conference on Communication in Healthcare (see other achievements).

What do you plan to do during the next reporting period to accomplish the goals?

We are completing the manuscript on the retrospective review of all adult patients seeking VCA evaluation between January 1, 2011, and February 28, 2020, and plan to submit this for publication. We are finalizing the manuscript on our findings related to VCA providers’ qualitative interviews titled “*Unique Aspects of Candidate Selection for Vascularized-Composite Allograft Transplantation: A Qualitative Inquiry of Transplant Providers*” and preparing this manuscript for submission. By the end of the next reporting period, we will have a completed manuscript discussing emerging themes about hand transplants from 10 interviews with people with limb loss. This paper will build off the current literature on patient perspectives about hand transplant, especially the thematic map published by Kinsey et al. (2021) and provide recommendations for clinicians about patient selection for hand transplant and factors contributing to the decision-making process. We plan to complete the development of the prototype for the conversation aid.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Due to the ongoing nature of the research, we believe that the impact of our findings will continue through the next year as we finalize our analysis of the qualitative data and complete the prototype of the conversation aid to facilitate decision making for transplant eligible individuals.

Three manuscripts based on data collected for Aim 1 are well underway. The first paper focuses on team science for VCA care. VCA requires multiple teams from multiple disciplines to work interdependently. Teams engage in a complex process of communication, coordination, and innovative and timely problem solving. They must maintain a high level of respect, flexibility, and confidence in each other and in the patient. This paper explores the organization of these processes and their perceived influence on patients progressing through stages for transplant. The second paper examines perceptions on treatment choices by key provider stakeholder groups, including providers at military and veteran facilities, prosthetists, and specialized transplant centers. It explores both formal and informal approaches for assessing patient needs, suitability for treatment, and attitudes and provider beliefs about available treatment options. The third paper is a case series focusing on the decision-making process of previous hand transplant candidates.

What was the impact on other disciplines?

This will occur once we have developed the conversation aid, which may result in new communication strategies for a variety of transplant team members as well as other individuals who provide care for patients with upper

extremity limb loss and facial disfigurement. We have had interest from physiatrists and prosthetists about how this research could aid them in their interactions with individuals who might be interested in hand or face transplantation.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

Over the last 2 years, we changed our recruitment approach to electronic consenting to help speed up recruitment and to help social distancing policies that were put in place during the height of the COVID-19 pandemic. Although COVID has made it more difficult to recruit subjects, we continue to have success in recruiting patients through word of mouth, snowball sampling and self-referral, and are actively sharing information about our study with a number of groups who either provide services to potential subjects or to caregivers. One such group is a prosthetics company that is going to share our study flyer with their Midwest sites to try to increase our recruitment numbers.

Actual or anticipated problems or delays and actions or plans to resolve them

We continue to anticipate that the recruitment will be a challenge due to the nature of the population who are often receiving care in prosthetic settings and may not be as accessible in medical settings where we have strong relationships with a number of medical providers.. COVID-19 continues to be a slight bump in recruitment as well, but we have been able to add changes into our processes to make the study still be able to function; examples include electronic consenting and zoom interviews.

Changes that had a significant impact on expenditures.

Nothing to report.

Significant changes in use of care of human subjects, vertebrate subjects, vertebrate animals, biohazards, and/or select agents.

Nothing to report.

Significant changes in use or care of human subjects.

Nothing to report.

Significant changes in use or care of vertebrate animal.

Nothing to report.

Significant changes in use of biohazards and/or select agents.

Nothing to report.

6. PRODUCTS

Publications, conference papers, and presentations

Publications: None

Abstracts: “*The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations*” was submitted to the International Conference on Communication in Healthcare. We submitted, with our colleagues in VCA at other centers, two abstracts for the American Transplant Congress 2022 on shared decision making, training of organ procurement organization professionals, and public service campaigns to increase VCA awareness and as well as an In-Depth Symposium on psychosocial issues of candidates, the role of family members and caregivers, shared decision-making tools, and postoperative outcomes.

Past Presentations

Session Title: Unlocking Concepts of VCA vs Solid Organ Transplant

Presentation Title: How Qualitative Research Informs Clinical Decision Making in VCA

Date: June 5, 2019

Venue: American Transplant Congress, Boston, MA

This presentation reviewed key concepts in the role that qualitative research can play in assisting the VCA scientific community in understanding the preferences, values, and motivation of affected individuals who may be interested in pursuing VCA as a treatment option.

Presentations Title: Hand transplantation and presentation on the DOD Funded Research Project “Potential VCA Candidates, Caregivers and Provider’s Motivations, Expectations and Shared Decision-Making in VCA”

Date: September 12, 2019

Venue: The National Center for Medical Rehabilitation Research (NCMRR), National Institute of Child Health and Human Development (NICHD) Limb Loss and Preservation Registry Meeting, Rochester, MN

Presentation Title: Progress Report (Chauvet Working Group)—Psychological Aspects in VCA

Date: October 1, 2019

Venue: International Society of Vascularized Composite Allotransplantation, New Delhi, India

Presentation Title: IMPACT Session: Psychosocial and Bioethical Aspects of VCA: An Update on Medical Decision Making for VCA Candidates

Date: June 5, 2021

Venue: American Transplant Congress (held virtually)

Presentation Title: The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations

Date: October 20, 2021

Venue: International Conference on Communication in Healthcare (held virtually)

Website(s) or other Internet site(s).

Nothing to report.

Technologies or techniques.

We are utilizing qualitative research strategies for Aim 1 analysis; for Aim 2 we are developing the digital Shared Decision-Making Tool, accessible through tablets or computers, intended to be used within patient-clinician interactions, as a means of structuring those conversations by calling attention to important decisive issues in VCA decision making. It is also intended to be used by candidates or potential candidates, with or without caregivers, at home as they consider and deepen their understanding of VCA and its implications and demands. Candidate-specific important topics that come up over the extended decision-making process can be added to the tool, expanded, and reflected upon.

Inventions, patent applications, and or licenses.

Nothing to report.

Other products.

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Sheila Jowsey-Gregoire
Project Role: Principal Investigator
Researcher Identifier:
Nearest person month worked: 5
Contribution to the Project: no change

Name: Adam Miller
Project Role: Study Coordinator
Researcher Identifier:
Nearest person month worked: 5
Contribution to the Project: no change

Name: Katrina Schaefer
Project Role: Research Protocol Specialist
Researcher Identifier:
Nearest person month worked: 0
Contribution to the Project: no change

Name: Joan Griffin
Project Role: Co-Investigator
Research identifier:
Nearest person month worked: 4
Contribution to the project: no change

Name: Karen Schaepe
Project Role: Research Analyst
Research Identifier:
Nearest person month worked: 3
Contribution to the project: no change

Name: Dawn Finnie
Project Role: Research Analyst and Qualitative Research Coordinator
Research Identifier: Assisted in research analysis of qualitative research activities.
Nearest person month worked: 1
Contribution to the project: no change

Name: Julie Gecox Hanson
Project Role: Study Coordinator
Researcher Identifier:
Nearest person month worked: 1
Contribution to the Project: Under the direction of PI, work on study modifications at our site. Prescreened study subjects.

Name: Kasey Boehmer
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 4
Contribution to the Project: Led team in beginning Aim 2 activities including necessary protocol modifications, reviewing Aim 1 data, and conducting Aim 2 qualitative chart review of past VCA candidates at Mayo Clinic.

Name: Ian Hargraves
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 5
Contribution to the Project: Contributed to Aim 1 and Aim 2 project planning and interpretation of Aim 1 data in preparation for the design activities of Aim 2.

Name: Fantley (Clay) Smither
Project Role: Co-Investigator
Research Identifier:
Nearest person month worked: 1
Contribution to the project: Help identify subjects in the Hand Clinic.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No

What other organizations were involved as partners?

None

8. SPECIAL REPORTING REQUIREMENTS

See Appendix 2 for Quad Report.

9. APPENDICES

Appendix 1. Enrollment Table

	Screened	Approached	Consented	Enrolled	Interviewed	Withdrew
Transplanted	11	6	5	5	5	
Transplanted Caregiver	2	0	0	0	0	
Candidate	10	9	2	1	1	
Candidate Caregiver	7	4	3	1	1	
Eligible	56	31	13	10	10	1
Eligible Caregiver	9	8	7	6	6	1
Provider	35	23	18	18	18	
Totals	131	84	50	44	44	2

Appendix 2: Year 3, Quarter 4, Quad Report
 Potential VCA Candidates, Caregivers and Provider's Motivations, Expectations and Shared
 Decision-making in VCA

Year 3 Quarter 4

Award Number: W81XWH1810676

PI: Dr. Sheila Jowsey-Gregoire

Org: Mayo Clinic Rochester

Award Amount: \$999,284.00



Study/Product Aim(s)

- To determine, through in-depth interviews, the motivations, values, preferences, and expectations of VCA candidates and their caregivers
- To incorporate the psychosocial and situational factors from Aim 1 in a Conversation Decision Aid to support military personnel and their care teams choose the appropriate treatment choice for their upper limb amputation and/or facial disfigurement.

Approach

- Obtain IRB approvals from our designated centers
- Conduct interviews that will help us better understand the motivations and values of the VCA patients.
- Use our information gathered to develop a Conversation Decision Aid to support the military VCA patients.

- Have been utilizing electronic consenting.*
- Enrollment and interviews continue.*
- Continue to video record subject appointments for Aim 2*
- Received a no cost extension*

Accomplishment: Place a description of the latest scientific accomplishment here. Limit the comments to three lines or less to make them fit; be succinct. These comments are valuable since they show progress.

Timeline and Cost

Activities	CY	18	19	20	21	22
Obtain Mayo Clinic IRB approval						
Obtain approval from HRPO						
Enroll and interview subjects, complete analysis of those interviews)						
Continue to develop a prototype decision aid						
Estimated Budget (\$K)		\$80	\$306	\$710	\$749	\$999

Updated: (10/27/2021)

Goals/Milestones

CY18 Goal – Start getting Approval from IRB

CY19 Goals – Attain Approvals and enroll subjects

CY20 Goal – Continue to activate AIM 2

Continue enrollment and interviewing of subjects

Obtain approval for external electronic consenting.

Obtain approval for Aim 2

CY21 Goal –

Reach our enrollment goal

Development and testing of the shared decision-making intervention.

Comments/Challenges/Issues/Concerns

• Being able to get in touch with Military and VA population.

• Obtained a no cost extension for another year

Budget Expenditure to Date

Projected Expenditure: \$749,463 (Adjusted due to NCE)

Actual Expenditure: \$818,580